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NOTICE OF ALLOWANCE AND FEE(S) DUE

3624

7590

08/08/2008

VOLPE AND KOENIG, P.C. UNITED PLAZA, SUITE 1600 30 SOUTH 17TH STREET PHILADELPHIA, PA 19103 EXAMINER

LOEWE, SUN JAE Y

ART UNIT PAPER NUMBER

1626 DATE MAILED: 08/08/2008

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 10/576,386 | 04/19/2006 | Girii Pal Singh | SMC-PT009 | 3611 |

TITLE OF INVENTION: NOVEL METHOD FOR PREPARATION OF CRYSTALLINE PERINDOPRIL ERBUMINE

| APPLN. TYPE | SMALL ENTITY | ISSUE FEE DUE | PUBLICATION FEE DUE | PREV. PAID ISSUE FEE | TOTAL FEE(S) DUE | DATE DUE |
|----------------|--------------|---------------|---------------------|----------------------|------------------|------------|
| nonprovisional | NO | \$1440 | \$300 | \$0 | \$1740 | 11/10/2008 |

THE APPLICATION IDENTIFIED ABOVE HAS BEEN EXAMINED AND IS ALLOWED FOR ISSUANCE AS A PATENT. PROSECUTION ON THE MERITS IS CLOSED. THIS NOTICE OF ALLOWANCE IS NOT A GRANT OF PATENT RIGHTS. THIS APPLICATION IS SUBJECT TO WITHDRAWAL FROM ISSUE AT THE INITIATIVE OF THE OFFICE OR UPON PETITION BY THE APPLICANT. SEE 37 CFR 1.313 AND MPEP 1308.

THE ISSUE FEE AND PUBLICATION FEE (IF REQUIRED) MUST BE PAID WITHIN THREE MONTHS FROM THE MAILING DATE OF THIS NOTICE OR THIS APPLICATION SHALL BE REGARDED AS ABANDONED. THIS STATUTORY PERIOD CANNOT BE EXTENDED. SEE 35 U.S.C. 151. THE ISSUE FEE DUE INDICATED ABOVE DOES NOT REFLECT A CREDIT FOR ANY PREVIOUSLY PAID ISSUE FEE IN THIS APPLICATION. IF AN ISSUE FEE HAS PREVIOUSLY BEEN PAID IN THIS APPLICATION (AS SHOWN ABOVE), THE RETURN OF PART B OF THIS FORM WILL BE CONSIDERED A REQUEST TO REAPPLY THE PREVIOUSLY PAID ISSUE FEE TOWARD THE ISSUE FEE NOW DUE.

HOW TO REPLY TO THIS NOTICE:

I. Review the SMALL ENTITY status shown above.

If the SMALL ENTITY is shown as YES, verify your current SMALL ENTITY status:

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B. If the status above is to be removed, check box 5b on Part B - Fee(s) Transmittal and pay the PUBLICATION FEE (if required) and twice the amount of the ISSUE FEE shown above, or

If the SMALL ENTITY is shown as NO:

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B. If applicant claimed SMALL ENTITY status before, or is now claiming SMALL ENTITY status, check box 5a on Part B - Fee(s) Transmittal and pay the PUBLICATION FEE (if required) and 1/2 the ISSUE FEE shown above.

II. PART B - FEE(S) TRANSMITTAL, or its equivalent, must be completed and returned to the United States Patent and Trademark Office (USPTO) with your ISSUE FEE and PUBLICATION FEE (if required). If you are charging the fee(s) to your deposit account, section "4b" of Part B - Fee(s) Transmittal should be completed and an extra copy of the form should be submitted. If an equivalent of Part B is filed, a request to reapply a previously paid issue fee must be clearly made, and delays in processing may occur due to the difficulty in recognizing the paper as an equivalent of Part B.

III. All communications regarding this application must give the application number. Please direct all communications prior to issuance to Mail Stop ISSUE FEE unless advised to the contrary.

IMPORTANT REMINDER: Utility patents issuing on applications filed on or after Dec. 12, 1980 may require payment of maintenance fees. It is patentee's responsibility to ensure timely payment of maintenance fees when due.

PART B - FEE(S) TRANSMITTAL

Complete and send this form, together with applicable fee(s), to: Mail Mail Stop ISSUE FEE

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| UNITED PLAZ | KOENIG, P.C. | | I he State | reby certify that the es Postal Service v | us Fee(s) Tr vith sufficie | ransmittal is being ent postage for first | deposited with the United class mail in an envelope |
| 30 SOUTH 17T | | | addr trans | essed to the Mai smitted to the USP | l Stop ISSU TO (571) 27 | UE FEE address a 73-2885, on the da | bove, or being facsimile indicated below. |
| PHILADELPHI | A, PA 19103 | | | | | | (Depositor's name) |
| | | | | | | | (Signature) |
| | | | | | | | (Date) |
| APPLICATION NO. | FILING DATE | | FIRST NAMED INVENTOR | | ATTORNE | Y DOCKET NO. | CONFIRMATION NO. |
| 10/576,386 | 04/19/2006 | • | Girij Pal Singh | | SMe | C-PT009 | 3611 |
| TITLE OF INVENTION | N: NOVEL METHOD FO | OR PREPARATION OF C | CRYSTALLINE PERINDO | PRIL ERBUMIN | E | | |
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| nonprovisional | NO | \$1440 | \$300 | \$0 | | \$1740 | 11/10/2008 |
| EXAM | MINER | ART UNIT | CLASS-SUBCLASS | | | | |
| LOEWE, S | SUN JAE Y | 1626 | 514-419000 | | | | |
| 1. Change of correspond CFR 1.363). | ence address or indicatio | n of "Fee Address" (37 | 2. For printing on the p | | | 1 | |
| Change of corresp | oondence address (or Cha B/122) attached. | inge of Correspondence | (1) the names of up to 3 registered patent attorneys or agents OR, alternatively, (2) the name of a single firm (having as a member a registered attorney or agent) and the names of up to | | | | |
| _ | lication (or "Fee Address | | | | | | |
| | 02 or more recent) attack | | 2 registered patent attorneys or agents. If no name is 3 listed, no name will be printed. | | | | |
| 3. ASSIGNEE NAME A | ND RESIDENCE DATA | A TO BE PRINTED ON | I THE PATENT (print or typ | pe) | | | |
| PLEASE NOTE: Un | less an assignee is ident | ified below, no assignee | data will appear on the pa T a substitute for filing an | atent. If an assign | ee is identi | fied below, the do | cument has been filed for |
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| Please check the appropri | riate assignee category or | categories (will not be pr | rinted on the patent): | Individual 🖵 Co | orporation o | or other private grou | p entity Government |
| 4a. The following fee(s) | are submitted: | 41 | o. Payment of Fee(s): (Plea | se first reapply a | ny previous | sly paid issue fee s | hown above) |
| Issue Fee | | | ☐ A check is enclosed. ☐ Payment by credit card. Form PTO-2038 is attached. | | | | |
| ☐ Publication Fee (No small entity discount permitted) ☐ Advance Order - # of Copies | | | The Director is hereby authorized to charge the required fee(s), any deficiency, or credit any | | | | |
| | | | overpayment, to Depo | sit Account Numb | er | (enclose an | extra copy of this form). |
| 5. Change in Entity Sta | i tus (from status indicate ns SMALL ENTITY stati | · · · · · · · · · · · · · · · · · · · | ☐ b. Applicant is no long | er claiming SMA | LL ENTITY | Y status. See 37 CF | R 1.27(g)(2). |
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| interest as shown by the | records of the United Sta | ites Patent and Trademark | Office. | | | | |
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| Typed or printed name | | | | Registration N | No | | |
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| an application. Confiden submitting the complete | duality is governed by 35 dapplication form to the | U.S.C. 122 and 3/ CFR USPTO. Time will vary | 1.14. This collection is est depending upon the indive Chief Information Office | imated to take 12 idual case. Any co | minutes to comments on | complete, including the amount of tim | gatnering, preparing, and e you require to complete |
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| Alexandra, Virginia 223 | 113-1430. | | | | | | |

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| 3624 75 | 90 08/08/2008 | | EXAM | INER | |
| VOLPE AND KOENIG, P.C. | | | LOEWE, SUN JAE Y | | |
| UNITED PLAZA, SUITE 1600 | | | ART UNIT | PAPER NUMBER | |
| 30 SOUTH 17TH STREET PHILADELPHIA, PA 19103 | | | 1626 DATE MAILED: 08/08/2008 | | |

Determination of Patent Term Adjustment under 35 U.S.C. 154 (b)

(application filed on or after May 29, 2000)

The Patent Term Adjustment to date is 167 day(s). If the issue fee is paid on the date that is three months after the mailing date of this notice and the patent issues on the Tuesday before the date that is 28 weeks (six and a half months) after the mailing date of this notice, the Patent Term Adjustment will be 167 day(s).

If a Continued Prosecution Application (CPA) was filed in the above-identified application, the filing date that determines Patent Term Adjustment is the filing date of the most recent CPA.

Applicant will be able to obtain more detailed information by accessing the Patent Application Information Retrieval (PAIR) WEB site (http://pair.uspto.gov).

Any questions regarding the Patent Term Extension or Adjustment determination should be directed to the Office of Patent Legal Administration at (571)-272-7702. Questions relating to issue and publication fee payments should be directed to the Customer Service Center of the Office of Patent Publication at 1-(888)-786-0101 or (571)-272-4200.

| | Application No. | Applicant(s) |
|--|--|---|
| | 10/576,386 | SINGH ET AL. |
| Notice of Allowability | Examiner | Art Unit |
| | SUN JAE Y. LOEWE | 1626 |
| The MAILING DATE of this communication appe All claims being allowable, PROSECUTION ON THE MERITS IS herewith (or previously mailed), a Notice of Allowance (PTOL-85) NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RI of the Office or upon petition by the applicant. See 37 CFR 1.313 | ears on the cover sheet with the (OR REMAINS) CLOSED in this a or other appropriate communication GHTS. This application is subject | correspondence address pplication. If not included on will be mailed in due course. THIS |
| 1. This communication is responsive to <u>7-15-2008</u> . | | |
| 2. The allowed claim(s) is/are <u>1</u> . | | |
| 3. | been received. been received in Application No. cuments have been received in this cuments have been received in this of this communication to file a replication. itted. Note the attached EXAMINE is reason(s) why the oath or declarst be submitted. on's Patent Drawing Review (PTC is Amendment / Comment or in the me header according to 37 CFR 1.12 is it of BIOLOGICAL MATERIAL | s national stage application from the y complying with the requirements R'S AMENDMENT or NOTICE OF ration is deficient. D-948) attached Office action of vings in the front (not the back) of 1(d). must be submitted. Note the |
| Attachment(s) 1. Notice of References Cited (PTO-892) 2. Notice of Draftperson's Patent Drawing Review (PTO-948) 3. Information Disclosure Statements (PTO/SB/08), Paper No./Mail Date 4. Examiner's Comment Regarding Requirement for Deposit of Biological Material | 5. Notice of Informal 6. Interview Summar Paper No./Mail D 7. Examiner's Amend 8. Examiner's Staten 9. Other | y (PTO-413), ate |

Application/Control Number: 10/576,386 Page 2

Art Unit: 1626

DETAILED ACTION

1. Claim 1 pending in the instant application.

Response to Amendment

2. The amendments to the claims filed on July 15, 2008 have been fully considered. The 35 USC 112 1st paragraph rejection is obviated, and hereby withdrawn.

Reasons for Allowance

3. The following is an examiner's statement of reasons for allowance. The instant process of preparing crystalline form of perindopril erbumine (characterized by the XRD pattern of claim 1) using N,N-dimethylformamide, dimethoxymethane, 2,2-dimethoxypropane, or 1,2-dimethoxyethane is novel and non-obvious over the prior art. The closest references teach alternate crystallization solvents, for example, ethyl acetate (WO 01/87835).

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Conclusions

- 4. Claim 1 allowed.
- 5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to SUN JAE Y. LOEWE whose telephone number is (571)272-9074. The examiner can normally be reached on M-F 7:30-5:00 Est.

Application/Control Number: 10/576,386 Page 3

Art Unit: 1626

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph McKane can be reached on (571)272-0699. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Sun Jae Y. Loewe, Ph.D./ 7-28-2008

/Kamal A Saeed, Ph.D./ Primary Examiner, Art Unit 1626